REMARKS

The Final Office Action mailed November 12, 2009, has been received and reviewed. Claims 25-30, 55-60, 85-89 and 91-93 are pending in the subject application. Claims 85-89 stand rejected under 35 U.S.C. § 101 and claims 25-30, 55-60, 85-89, and 91-93, stand rejected under 35 U.S.C. § 103(a). In response, it is proposed that each of independent claims 25, 55, 85, and 91, be amended as set forth herein. As such, upon entry of this Reply, the proposed amendments will become actual and entered amendments. Claims 25-30, 55-60, 85-89, and 91-93 will remain pending. It is submitted that no new matter has been added by way of the present proposed amendments. Reconsideration of the subject application is respectfully requested in view of the proposed amendments and the following remarks.

Rejections based on 35 U.S.C. § 101

Claims 85-89 stand rejected under 35 U.S.C. § 101 because these claims are drawn to non-statutory subject matter. Specifically, the Office indicates the definition of "computer storage media" in the Specification is expansive enough to include "signals," which are currently not considered to fall within the statutory classes of § 101.

In response, the definition of "computer storage media" in the Specification is amended to exclude the broad language that would encompass any form of communication media, such as a modulated signal or carrier wave. As such, claim 85 is limited to "computer storage media," which, by definition, encompasses tangible embodiments of media storage (e.g., RAM, ROM, EEPROM, flash memory, DVD's, CD-ROM, and the like). Because computer storage media is now directed toward physical memory—as opposed to communication media that may include information-delivery media—claim 85 is limited to physical memory.

As computer storage media is directed toward tangible embodiments, claim 85 is limited to statutory subject matter. "When functional descriptive material is recorded on some

computer-readable medium, it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since the use of technology permits the function of the descriptive material to be realized."[1] Claim 85 is directed to computer-executable instructions embedded on "computer storage media" that stores a data structure and, thus, constitutes physical articles that fall within the statutory classes. That is, amended claim 85 relates to media encoded with a data structure that defines structural and functional interrelationships between the data structure of the computer software and hardware components. This permits the data structure's functionality to be realized.

Accordingly, it is respectfully submitted that amended claim 85 is limited to tangible embodiments and, thus, is directed toward statutory subject matter. Further, each of claims 86-89 are believed to be in condition for allowance based, in part, upon their dependency from independent claim 85, and such favorable action is respectfully requested.[2]

Rejections based on 35 U.S.C. § 103

A.) Applicable Authority

The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure.[3] To establish a *prima facie* case of obviousness, all the claim limitations must be taught by the prior art.[4] "All words in a claim must be considered in judging the patentability of that claim against the prior art."[5]

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[1] MPEP § 2106.01. *See*, *In re Lowry*, 32 F.3d 1579, 1583-84 (Fed. Cir. 1994) (discussing patentable weight of data structure stored on a computer readable medium that increases computer efficiency); s*ee also*, *In re Warmerdam*, 33 F.3d 1354, 1360-61 (discussing patentable weight of data structure limitations in the context of a statutory claim to a data structure stored on a computer readable medium that increases computer efficiency).
[2] *See* 37 C.F.R. § 1.75(c) (2006).
[3] *See* MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).
[4] MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974).
[5] MPEP § 2143.03; *In re Wilson*, 57 C.C.P.A. 1029, 1032 (1970)

B.) Unpatentable Rejection based on Ichikawa in view of Evans et al., U.S. Publication No. 2002/0049772 to Reinhoff, U.S. Publication No. 2002/0038227 to Fey, and U.S. Publication No. 2002/0110823 to Hogan

Claims 25-30, 55-60, 85-89, and 91-93 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ichikawa,[6] in view of Evans et al.[7] (hereinafter Evans), Reinhoff et al.[8] (hereinafter Reinhoff), Fey et al.[9] (hereinafter Fey) and Hogan.[10] As the Ichikawa reference, the Evans reference, the Reinhoff reference, the Fey reference, and the Hogan reference, whether taken alone or in combination, fail to teach or suggest all of the limitations of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claim 25, as amended herein, recites a computer-implemented method for processing hereditary data related to the use of clinical agents by a person. In particular, the method includes displaying a GUI on a display device, wherein the GUI is configured to output "an interpretation of the genetic test result value and the list of risk-associated agents," where "outputting comprises showing to the clinician a notification window that displays the list of risk-associated agents, a warning of effects of the polymorphism value, and alternate clinical agents that are not associated with the polymorphism value." Further, GUI includes "*a button* that, when selected, *directs the clinician to addition information regarding the association of the clinical agent and a genetic mutation linked to the polymorphism value*" (emphasis added). In this way, a specific configuration of a notification window is claimed that presents each of the following: a warning of effects of the polymorphism value; alternate clinical agents that are not associated with the polymorphism value; and a button that directs the clinician

[6] *Internal Medicine* (July 2000) Vol. 39, No. 7, pp. 523-524.
[7] *Science* (October 1999) Vol. 286, pp. 487-491.
[8] U.S. Publication No. 2002/0049772.
[9] U.S. Publication No. 2002/0038227.
[10] U.S. Publication No. 2002/0110823.

to addition information regarding the association of the clinical agent and a genetic mutation linked to the polymorphism value.

The Office indicates that the primary reference, Ichikawa, the Evans reference and the Fey reference do not teach generating a GUI with a notification window that displays either the (a) "effects of the polymorphism value" or (b) the "alternate clinical agents . . . not associated with the polymorphism value." Further, the Office indicates that the Reinhoff reference does not explicitly recite the GUI having the specific functionality as claimed. However, the Office states that Reinhoff at paragraph [0010] teaches a computer program that allows identification of a susceptibility locus in individuals using genetic screening. But, Reinhoff does not describe automatically generating a GUI with the notification window that displays the values (a) and (b), as well as the "button that . . . directs the clinician to addition information regarding the association of the clinical agent and a genetic mutation linked to the polymorphism value."

In view of the above, it is asserted that the combination of the Ichikawa, Evens, Reinhoff, Fey, and Hogan references does not teach or suggest the specific values (a) and (b), or the button the directs a clinician to specific information, of the notification window of the GUI recited by claim 25. As such, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of independent claim 25, as amended, be withdrawn. Each of claims 26-30 and 92 depend, either directly or indirectly, from independent claim 25. As such, these claims are believed to be in condition for allowance at least by virtue of their dependency.[11] Consequently, withdrawal of the obviousness rejection and allowance of claims 25-30 and 92 are respectfully requested.

[11] *See* 37 C.F.R. § 1.75(c) (2006).

Independent claim 55 has been amended herein to recite a new process for determining whether to request authorization from a physician/clinician to order a genetic test, or whether to automatically order the genetic test without a request for approval. This new process involves the following steps: "upon determining that a gene is associated with a clinical agent," "automatically obtaining a genetic test result value for the associated gene of the patient" by "(a) receiving from the displaying component identification of the patient to whom the clinical agent is to be administered and proper authorization to access an electronic medical record (EMR) of the patient; and (b) utilizing the identification and the proper authorization from the clinician to access patient information within the EMR of the patient stored within a comprehensive healthcare system." Upon determining that the genetic test result value for the patient is not available in the EMR, "obtaining a genetic test result value for the associated gene of the patient" by "(a) *determining whether to request authorization from a clinician to carry out the genetic test based on three criteria, a cost of the genetic test, whether the genetic test is available, and a likelihood of a genetic variation based on demographic information of the patient*; (b) when the three criteria indicate authorization is needed, seeking the clinician's authorization for the genetic test by displaying a genetic test ordering window at the GUI; and (c) when the three criteria indicate no authorization is needed, automatically ordering the genetic test to determine the genetic test result value for the associated gene of the patient" (emphasis added). In this way, if the three criteria are met, the physician is solicited to authorize a genetic test. Otherwise, the genetic test is automatically ordered without soliciting input of the physician.

None of the cited portions of the Ichikawa reference, the Evans reference, the Reinhoff reference, or the Fey reference, whether taken alone or in combination, teach or suggest reviewing the three criteria used when determining whether to request a physician to authorize a genetic test. The Office indicates that Hogan describes these criteria. However, the Hogan

reference does not use these criteria for "determining whether to request authorization from a clinician to carry out the genetic test." Instead, Hogan looks at criteria (e.g., cost and effectiveness) to determine which assay technique to administer in order to generate a genomic profile of the patient.[12] As such, Hogan does not consider using criteria for choosing whether to ask for approval to administer a test or not. Differently, Hogan uses the criteria for determining the type of test that will be administered. Moreover, the criteria used by Hogan do not directly correspond to the three criteria claimed in claim 55.

Accordingly, for at least this reason, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of independent claim 55, as amended, be withdrawn. Each of claims 56-60 depend, either directly or indirectly, from independent claim 55. As such, these claims are believed to be in condition for allowance at least by virtue of their dependency.[13] Consequently, withdrawal of the obviousness rejection and allowance of claims 55-60 are respectfully requested.

Independent claim 85 has been amended herein to expand upon the method of soliciting authorization from the clinician to carry out the genetic test, "when the genetic test result is unavailable" in the EMR. Specifically, this method is divided into two main processes based on the availability of personal information of the patient. "When personal information about the person is accessible," the method involves "performing the steps comprising: (a) *utilizing the personal information about the person for calculating a first likelihood that the person displays genetic variability* linked with genes associated with the genetic test, wherein the personal information includes one or more demographic factors; and (b) displaying a notification window in the GUI that solicits authorization from the clinician to carry out the genetic test,

[12] Hogan at ¶ [0187].
[13] *See* 37 C.F.R. § 1.75(c) (2006).

wherein *the notification window presents the first likelihood* that the person displays genetic variability linked with genes" (emphasis added).

"When the genetic test result is unavailable and when the personal information about the person is inaccessible," the method involves "performing the steps comprising: (a) *utilizing genetic variability of a general population for calculating a second likelihood* that the person displays genetic variability linked with genes associated with the genetic test; and (b) displaying the notification window in the GUI that solicits authorization from the clinician to carry out the genetic test, wherein *the notification window presents the second likelihood* that the person displays genetic variability linked with genes" (emphasis added). In this way, a very specific decision tree is implemented as an algorithm in the computer system recited in claim 85. Further, the decision tree, or arbitrage process, first looks for personal information (e.g., demographic factors that describe the patient), and then for general population information (no specific patient information necessary) to identify a first or second likelihood, respectively, that a patient has a genetic variability. Even further, as a result of the decision tree, the first or second likelihood that a patient has a genetic variability is displayed in a notification window that solicits authorization from the clinician to carry out the genetic test.

None of the cited portions of the Ichikawa reference, the Evans reference, the Reinhoff reference, and the Fey reference, whether taken alone or in combination, teach or suggest a decision tree that:

1. Initially, looks for a genetic test result value in an EMR;

2. If no genetic test result value is found, looks for a personal information of the patient to determine a "first likelihood;"

3. If no personal information of the patient is found, looks for genetic variability of the general population to determine a "second likelihood;"

4. Displays the first or second likelihood in the context of a request for authorization to carry out the genetic test.

Further, the Hogan reference does not describe the decision tree above. Instead, Hogan describes using criteria for determining which type of test to administer in accordance with which test is most cost-effective, efficient, safe, etc.[14] As such, there is no consideration of performing a decision tree simply to solicit authorization to perform the test in Hogan. Moreover, the Hogan reference does not consider generating and displaying either a first or a second likelihood in a notification window in tandem with a solicitation for genetic-test authorization, in order to provide the clinician with relevant information for approving the genetic test. Accordingly, for at least this reason, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of independent claim 85, as amended, be withdrawn. Each of claims 86-89 depend, either directly or indirectly, from independent claim 85. As such, these claims are believed to be in condition for allowance at least by virtue of their dependency.[15] Consequently, withdrawal of the obviousness rejection and allowance of claims 85-89 are respectfully requested.

Claim 91 has been amended herein to clarify the method of determining whether to automatically generate a low-risk clinical response or a high-risk clinical response, as well as the actions to be conducted for each response. In particular, the method is invoked "when the person has been exposed to one or more of the agents on the list of risk-associated agents." Upon invocation, the method involves "ascertaining whether to automatically generate a low-risk

[14] Hogan at ¶ [0187].

clinical response or a high-risk clinical response based on whether a dosage of the one or more agents exceeds a predetermined dangerous level."

"When the person has been exposed to a dosage of the one or more agents on the list of risk-associated agents that is above the predetermined dangerous level, automatically generating the high-risk clinical response." The actions that occur upon generating a high-risk clinical response include "(a) reducing the dosage of the agent to an amount below the predetermined dangerous level; and (b) placing an alternative order for an agent that is absent from the list of risk-associated agents."

"Otherwise, automatically generating the low-risk clinical response that includes performing the actions" including "(a) adding a comment to the person's electronic medical record indicating that no risks were determined from the genetic test result value; and (b) outputting an interpretation at the GUI of the low-risk clinical response, wherein the interpretation indicates the genetic test result value is not associated with any know risks."

In this way, the decision of whether conduct a low-risk or high-risk clinical response is based on two criteria (i.e., whether the person has been exposed to an agent on the list of risk-associated agents, and whether a dosage of the agent exceeds a predetermined dangerous level). Further, once the decision to conduct the low-risk or high-risk clinical response is made, there are specific actions that are grouped with each response.

Initially, the Office states that Fey does not explicitly teach ascertaining whether to automatically generate a low-risk or high-risk clinical response based on patient exposure to one or more risk-associated agents. Yet, the Office contends that the decision to implement a high-risk or low-risk clinical response is obvious "because the goal of the health data

[15] *See* 37 C.F.R. § 1.75(c) (2006).

management system is to enable a consumer/client to better monitor their health at a genetic level."[16]

However, the Office does not address the second criteria of whether a "person has been exposed to a dosage of the one or more agents on the list of risk-associated agents that is above the predetermined dangerous level" to determine whether to automatically generate a low-risk or high-risk clinical response.

Further, once the determination is made, none of the cited references group the actions "(a) reducing the dosage of the agent to an amount below the predetermined dangerous level; and (b) placing an alternative order for an agent that is absent from the list of risk-associated agents" with the high-risk clinical response.

Even further, once the determination is made, none of the cited references group the actions "(a) adding a comment to the person's electronic medical record indicating that no risks were determined from the genetic test result value; and (b) outputting an interpretation at the GUI of the low-risk clinical response," where "the interpretation indicates the genetic test result value is not associated with any know risks," with the low-risk clinical response.

Further yet, the use of a dual-response system based of the two criteria mentioned above (i.e., implementing one specific grouping of actions (high-risk) or another specific grouping of actions (low risk)) was not inherent to the provision health care at the time of invention. Instead, using these two criteria is a new and advantageous way to use the results of the processes in claim 91 to affect the treatment of the patient.

Accordingly, for at least these reasons, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of independent claim 91, as amended, be withdrawn. Claim 93 depends from independent claim 91. As such, claim 93 is believed to be in condition for

[16] Office Action at pg. 13.

allowance at least by virtue of its dependency.[17] Consequently, withdrawal of the obviousness rejection and allowance of claims 91 and 93 are respectfully requested.

[17] *See* 37 C.F.R. § 1.75(c) (2006).

CONCLUSION

For at least the reasons stated above, upon entry of the amendments, it is believed that claims 25-30, 55-60, 85-89, and 91-93 will be in condition for allowance. As such, Applicants respectfully request entry of the amendments, withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or btabor@shb.com (such communication via email is herein expressly granted) – to resolve the same.

The fees for a One Month Extension of Time and Request for Continued Examination are submitted herewith. It is believed that no additional fee is due, however, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.83071.

Respectfully submitted,

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